

Appln. Serial No. 09/233,443

AMENDMENT AFTER FINAL REJECTION UNDER 37 CFR 1.116

Attorney Docket No. BVL-105

### REMARKS

Claims 21-22, 26, 29, 47-53, 55, 66-67, 96-111, 113, and 115 are pending herein. By this Amendment, non-rejected Claims 54, 57, 112, and 114 are canceled, and independent Claims 21, 104, and 107 are amended. No new matter is added by this Amendment.

Applicants thank Examiner Webman for indicating that Claims 54, 57, and 110-115 recite allowable subject matter. Accordingly, Claim 57 is also pending, even though the Office Action indicates to the contrary.

#### I. RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

As the pending claims are allowable, search and examination must continue as to the non-elected species of encapsulants, such as enzymes and probiotics. Thus, withdrawn Claims 53, 98, and 100 have not been canceled.

#### II. REJECTION UNDER 35 U.S.C. 103(a)

Claims 21-22, 26, 29, 47-52, 55, 66-67, 96-97, 99, and 101-109 were rejected under 35 U.S.C. 103(a) over U.S. Patent No. 5,262,167 (Vegesna et al.) in view of U.S. Patent No. 5,716,615 (Cavaliere Vesely et al.), U.S. Patent No. 3,925,343 (Hampton et al.), and U.S. Patent No. 3,762,931 (Craig et al.). This rejection is respectfully traversed.

Vegesna et al. discloses a non-baked cholestyramine composition in which cholestyramine is in admixture with a carrier. The carrier is made up of a grain or flour, sugars, and starch binder, and may also contain an edible oil (Abstract). The composition comprises about 7 to about 20% by weight of one or more grain-based products (col. 2, lines 42-48). The total moisture of the composition should not exceed 11% by weight. The composition of Vegesna et al. is a compressed agglomerate, not a matrix in which the

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cholestyramine is encapsulated and substantially uniformly distributed. Vegesna et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient; (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material; or (3) a *lactobacilli* encapsulant.

Cavaliere Vesely et al. does not overcome the deficiencies of Vegesna et al. Cavaliere Vesely et al. discloses a pharmaceutical composition containing several different bacteria including *Streptococcus thermophilus* and *Lactobacillus plantarum* or *Lactobacillus casei*. Like Vegesna et al., Cavaliere Vesely et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient; or (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material. There is no teaching, suggestion, or motivation to combine Cavaliere Vesely et al. and Vegesna et al. The Examiner has not set forth any facts supporting the assertion that the addition of a *lactobacillus* agent to a non-baked cholestyramine composition would be expected to have a beneficial effect.

Hampton et al. does not overcome the deficiencies of Vegesna et al. and Cavaliere Vesely et al. Hampton et al. discloses converting wheat gluten into agglomerates under conditions that do not denature the gluten so that the gluten can be dispersed in water to form a relatively stable dispersion (Abstract). Hampton et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient or (2) a *lactobacilli* encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material.

Craig et al. does not overcome the deficiencies of Vegesna et al., Cavaliere Vesely et al., and Hampton et al. Craig et al. discloses a process for making macaroni (pasta) products including mixing and extruding a paste (Abstract). Craig et al. states that flour obtained from durum wheat is needed to make macaroni products under high pressure.

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See col. 1, lines. 13-25 and 31-39. There is no teaching or suggestion to substitute the durum wheat of Craig et al. for the pregelatinized starch binder in Vegesna et al. In fact, there is no reason why one of ordinary skill in the art would seek to use the durum wheat of a smooth, hard, glassy pasta or macaroni product as obtained in Craig et al. for the coarse, granola-like, chewable granules disclosed in Vegesna et al.

None of the cited references teaches or suggests the combination of: (1) at least one plasticized matrix material comprising a durum ingredient; (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material; and (3) a *lactobacilli* encapsulant.

Nevertheless to reduce the issues for prosecution, non-rejected Claim 54 is canceled and its subject matter is incorporated into independent Claim 21; non-rejected Claim 112 is canceled and its subject matter is incorporated into independent Claim 104; and non-rejected Claim 114 is canceled and its subject matter is incorporated into independent Claim 107. Claim 57 is canceled as being redundant. Reconsideration and withdrawal of the rejection are respectfully requested.

### III. DOUBLE PATENTING

To avoid any question of double patenting, Applicants will file a Terminal Disclaimer over copending U.S. Application No. 09/782,320 and U.S. Patent No. 6,500,463 B1 if required by the Examiner.

### IV. CONCLUSION

In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the

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undersigned would be appreciated since this should expedite the prosecution of the application.

Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #BVL-105).

Respectfully submitted,



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